Supreme Court, U.S.
FILED
OCT 13 2004
OFFICE OF THE CLERK

(18)

No. 03-1454

IN THE

Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

ANGEL MCCLARY RAICH, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals For the Ninth Circuit

Brief For Lymphoma Foundation of America; HIV Medicine Association of the Infectious Diseases Society of America; American Medical Student Association; Dr. Barbara Roberts; and Irvin Rosenfeld As *Amici Curiae* In Support of Respondents

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TABLE OF CONTENTS

Page

INTEREST OF AMICI CURIAE 1

SUMMARY OF ARGUMENT 1

ARGUMENT 4

I. RELIABLE RESEARCH AND CLINICAL EXPERIENCE PROVIDE A SOUND BASIS FOR THE MEDICAL USE OF MARIJUANA BY CERTAIN SERIOUSLY ILL PATIENTS 4

A. A U.S. Government Panel Concluded That Marijuana Is Effective And Medically Beneficial 4

B. Great Britain House of Lords Concluded that Marijuana Holds Medical Benefits for Certain Seriously Ill Patients 6

C. An Administrative Law Judge Likewise Concluded that Marijuana has Accepted Medical Uses 7

D. After Evaluating the Medical Evidence, Canada Now Permits Medical Marijuana 9

II. MARIJUANA HAS RECOGNIZED ANALGESIC, ANTIEMETIC, ANTI-INFLAMATORY, AND APPETITE-ENHANCING PROPERTIES 10

A. Marijuana Is An Effective Pain Killer 10

B. Marijuana Is Effective In Treating Nausea, Anorexia And Wasting 12

C. Marijuana Is Effective In Treating Muscle Spasticity 13

TABLE OF CONTENTS
(Continued)

Page

D. Marijuana Is Effective In Controlling Seizures 14

E. The Side Effects Of Marijuana Are No More Severe And Often Less Severe Than The Side Effects Of Many Currently Sanctioned Medications 15

III. SYNTHETIC THC IS APPROVED AS A PRESCRIPTION DRUG, BUT OFTEN IS NOT AS EFFECTIVE, DESIRABLE, OR SAFE AS SMOKING MARIJUANA 17

IV. THE PERSONAL EXPERIENCES OF BOTH MEDICAL PROVIDERS AND PATIENTS SUPPORT SCIENTIFIC AND GOVERNMENT FINDINGS THAT MARIJUANA CAN BE AN EFFECTIVE THERAPEUTIC 21

CONCLUSION 22

APPENDIX

TABLE OF AUTHORITIES

Page

Cases

Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) (Kozinski, J., concurring), *cert. denied*, 124 S. Ct. 387 (2003) 5

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Page

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Page

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Page

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INTEREST OF AMICI CURIAE*

Amici Curiae have personal or professional experience and expertise regarding medical, scientific and public health issues, and are united in their concern that this case be decided upon an accurate understanding of the medical and scientific facts.[1] There is overwhelming support for the legitimacy and efficacy – and sometimes unique therapeutic benefits – of herbal cannabis as medicine.

Amici are equally concerned that the Court understand that there are seriously ill patients who do not respond to or cannot tolerate conventional therapies. For these individuals, the art of medicine – the ability of health care professionals to work closely with them and fashion a treatment regimen tailored to their unique needs – assumes heightened importance.

SUMMARY OF ARGUMENT

A small but significant number of seriously ill patients who suffer from cancer, human immunodeficiency virus or Acquired Immune Deficiency, multiple sclerosis, epilepsy, chronic debilitating pain, spasticity, and other serious medical conditions, do not benefit from, or cannot tolerate the therapies of currently available conventional medicine. Many of these patients, like Respondents here, have found, together with their physicians, that marijuana effectively alleviates symptoms of their conditions and side effects caused by their primary treatments.

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*No counsel for any party authored any part of this brief. No person or entity, other than *Amici* and Savitt & Bruce LLP, made a monetary contribution toward submission of this brief, which is filed with parties' written consent.

[1] Descriptions of *Amici Curiae* are set forth in the Appendix to this brief.

The experiences of these patients and the observations of their physicians accord with the conclusions recently reached by blue ribbon government panels and in federally-funded, peer-reviewed scientific studies: that marijuana has therapeutic properties not replicated by other currently available medications. These studies have consistently found (1) that marijuana is an effective anti-inflammatory, analgesic, appetite-stimulating, antiemetic, and antispasmodic agent; (2) that its side effects are often less debilitating than those of drugs currently approved for treating the same ailments; and (3) that for some individuals it is the only meaningful option. For certain persons the medical use of marijuana can literally mean the difference between life and death. At a minimum, marijuana provides some seriously ill patients the gift of relative health and the ability to function as productive members of society.

Despite this convincing evidence, the federal government continues to impede individuals' access to marijuana for medical purposes – especially where those patients are cultivating or using it with the endorsement of their physician and entirely within states where its use is permitted under state law.[2]

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[2] To date a total of 26 States have recognized the medical benefits of cannabis in some form:

Nine States have enacted laws allowing medical use of cannabis. *See* Alaska Stat. §§ 11.71.090, 17.37.010 et seq. (Michie 2003); Cal. Health & Safety Code § 11362.5 (West Supp. 2004); Colo. Const. art. 18, § 4; Haw. Rev. Stat. Ann. § 329-121 et seq. (Michie Supp. 2003); Me. Rev. Stat. Ann. tit. 22, § 2383-B (West 2004); Nev. Rev. Stat. Ann. § 453A.200 (Michie Supp. 2003); Or. Rev. Stat. §§ 475.300-.346 (2003); Vt. Stat. Ann. tit. 18 § 4272 et seq. (2004); Wash. Rev. Code Ann. §§ 69.51.010-.080 (West 2004).

Five additional States have enacted laws recognizing the therapeutic benefits of cannabis but authorize use only by prescription, *see* Ariz. Rev. Stat. § 13-3412.01 (West 2004); La. Rev. Stat. Ann. § 40:1201 (West 2003); N.H. Rev. Stat. Ann. § 318-B:10(VI) (2003); Va. Code Ann. § 18.2-251.1 (Michie 2003), or classify cannabis as having "currently

Let it be clear: if the ruling of the Court of Appeals is not upheld, patients with debilitating, often life-threatening conditions not only will be deprived of an important and effective treatment option, they will be condemned to real and avoidable suffering.

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accepted medical uses," *see* Iowa Code §§ 124.205, 124.206(7)(a) (West 2003).

Two additional States have passed resolutions urging the federal government to allow the medical use of cannabis. *See* Mo. Sen. Con. Res. 14 (1994); N.M. Sen. Memorial 42 (1982), *available at* http://www.sumeria.net/nmcu/memorial.html.

Seven additional States have enacted laws recognizing cannabis's potential medical benefits for persons suffering from conditions including cancer, nausea, and glaucoma, and establishing therapeutic research programs for the benefit of such persons. *See* Ala. Code § 20-2-111 et seq. (1979); Ga. Code Ann. §§ 43-34-120 et seq. (1980); 720 Ill. Comp. Stat. 550/11 (1971); Mass. Gen. Law Sch. 94D, §§ 1-3 (1991); N.Y. Pub. Health Law §§ 3328(4), 3397-a to 3397-f (1980); Minn. Stat. § 152.21 (1980); S.C. Code Ann. §§ 44-53-620 et seq. (1980).

The courts of two additional States have allowed cannabis patients to raise a necessity defense to charges of marijuana possession. *See Sowell v. State*, 738 So.2d 333, 334 (Fla. Dist. Ct. App. 1998); *State v. Hastings*, 801 P.2d 563, 565 (Idaho 1990). A third State recently limited the penalty for possessing cannabis for medical purposes to a $100 fine. *See* Md. Code Ann., Crim. Law art. 5-601(c)(3).

This State legislation reflects strong popular support for medical use of cannabis in appropriate circumstances. See, e.g., Coleen McMurray, *Medicinal Marijuana: Is It What the Doctor Ordered?*, Gallup Poll Tuesday Briefing (Dec. 16, 2003) (75% of Americans support allowing physicians to prescribe cannabis to patients); The Polling Report, Inc., *Illegal Drugs*, http://www.pollingreport.com/drugs.htm (last visited October 11, 2004) (CNN/Time poll: 80 percent of Americans favor allowing adults to use cannabis for medical purposes on a physician's recommendation).

ARGUMENT

I. RELIABLE RESEARCH AND CLINICAL EXPERIENCE PROVIDE A SOUND BASIS FOR THE MEDICAL USE OF MARIJUANA BY CERTAIN SERIOUSLY ILL PATIENTS

Clinical experience and a growing body of medical research confirm that for a small but significant number of patients, marijuana serves as the *only* effective medicine for suppressing nausea, stimulating appetite, or relieving pain. *See e.g. Conant v. Walters*, 309 F.3d 629, 640-43 (9th Cir. 2002) (Kozinski, J., concurring), *cert. denied*, 124 S. Ct. 387 (2003) (summarizing the medical evidence supporting limited medical use of marijuana). Indeed, the scientific literature – and the highly respected research panels from the United States and Great Britain – make clear that there is widespread agreement that cannabis is effective in alleviating the symptoms of many patients who have not obtained relief from conventional treatments.[3]

A. A U.S. Government Panel Concluded That Marijuana Is Effective And Medically Beneficial

In 1997, largely in response to the passage of California's Compassionate Use Act[4], the White House

[3] In this vein, it should be noted that of the several briefs *amici curiae* filed on behalf of Petitioner, only one brief takes strong issue with notion that herbal cannabis can play a therapeutic role of herbal cannabis, *See Brief Amici Curiae* of Drug Free America Foundation, *et al.*, while the amicus brief submitted by nationally renowned physicians Robert DuPont and Herbert Kleber acknowledges the widespread and legitimate medical use of cannabis by patients residing in Canada and the Netherlands. *See Brief Amici Curiae* of Robert DuPont, M.D., *et al.*, at 26-27.

[4] Cal. Health & Safety Code § 11362.5 (West Suppl. 2001) (available online at http://www.leginfo.ca.gov/calaw.html).

Office of National Drug Control Policy commissioned the National Institute of Medicine of the National Academy of Sciences ("IOM")[5] to undertake an extensive review of the scientific evidence of the therapeutic applications of cannabis.[6] The IOM was tasked with assessing the current scientific findings concerning medical marijuana. In accomplishing its task, the IOM reviewed the scientific bases identifying the active ingredients of marijuana, how those ingredients act on human and animal physiology, and clinical experiments evaluating the efficacy of marijuana and several of its active agents. *Institute of Medicine Marijuana and Medicine: Assessing the Science Base*, (Janet E. Joy, et al, eds., National Academy Press 1999) ("IOM" Report), at 9.

The result of an exhaustive year-long study, which included scientific workshops, analysis of relevant scientific literature, and extensive consultation with biomedical and social scientists, was the 250-plus-page IOM Report, which concluded that "[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation." IOM report at 15, 179.

The IOM acknowledged that marijuana currently provides the only alternative for certain people for whom approved medicines are ineffective and emphasized the desirability of further research into the effects of cannabinoids and the development of systems by which the active ingredients of marijuana can be delivered to patients in a dose-controlled, smoke-free manner. IOM Report at 10-11, 179. As a result, it is not surprising that the IOM

[5] The IOM was chartered in 1970 by the National Academy of Sciences ("NAS") to bring professionals in different disciplines together to examine policy matters pertaining to the health of the nation. The IOM furthers NAS's responsibility to advise the federal government on such issues pursuant to an 1863 congressional charter.

[6] The complete IOM report is available at http://www.nap.edu/books/0309071550/html.

conditionally endorsed medical marijuana.[7] Additional examples of specific findings and studies relied on by the IOM are identified in Section II below.

B. Great Britain's House of Lords Concluded that Marijuana Holds Medical Benefits for Certain Seriously Ill Patients

While the IOM was conducting its evaluation, Great Britain's House of Lords was also conducting hearings and taking testimony from leading researchers, clinicians and patients regarding the medical benefits and drawbacks of cannabis.[8] The findings and recommendations of the Lords Report closely parallel those of the IOM. The House of Lords concluded that "cannabis almost certainly does have genuine medical applications, especially in treating the painful muscular spasms and other symptoms of MS and in the control of other forms of pain. Lords Report § 8.2 at 41. The House of Lords called for additional scientific studies into marijuana's medical value as well as identifying alternative modes of administration which would retain the benefit of rapid absorption offered by smoking, while minimizing any adverse effects. Lord Report §§ 8.1-8.4, at 41.

Given the state of current medical knowledge and anecdotal evidence attesting to the efficacy of marijuana, the House of Lords concluded that the government should act immediately 'to allow doctors to prescribe an appropriate preparation of cannabis, albeit as unlicensed medicine."[9]

C. An Administrative Law Judge Likewise Concluded that Marijuana has Accepted Medical Uses

In the late 1980's, the United States Department of Justice referred petitions seeking removal of marijuana from the list of Schedule I substances under the Controlled Substances Act,[10] to Francis L. Young, and Administrative Law Judge in the Drug Enforcement Administration. In September 1988, after more than two years of evidentiary hearings and other proceedings, Judge Young rendered an *Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge in the Matter of Marijuana Rescheduling Petition*, Docket No. 86-22 (Dep't Justice D.E.A., Sept. 6, 1988) (hereinafter, "ALJ Opinion").[11] Judge Young found that the

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[7] Specifically, the IOM Report suggested that:

> Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms...must meet the following conditions: [i] failure of all approved medications to provide relief has been documented, [ii] the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs, [iii] such treatment is administered under medical supervision in a matter that allows for assessment of treatment effectiveness, and [iv] involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

IOM Report at 179. While the IOM's statement ostensibly would limit the use of marijuana to six months' duration, in the context of the full report, it is apparent that the IOM does not urge the automatic termination of treatment at the arbitrary date, but rather recommends that patients' marijuana use be reevaluated on at least a semiannual basis. The authors' reluctance to approve the longer-term use of cannabis was based primarily on their concern about the possible pulmonary risks posed by smoking marijuana.

[8] Select Committee on Science and Technology, House of Lords, Sess. 1997-98, 9th Report, Cannabis: The Scientific and Medical Evidence (Nov. 4, 1998), available at http://www.publications.parliament.uk/pa/ld199798/ldselect/ldsctech/151/15101.htm ("Lord Report").

[9] Lord Report § 8.6 at 41. The United Kingdom, unlike the United States, allows physicians to prescribe an unapproved medicine to a particular patient, so long as certain conditions are followed. Se generally, Lord Report at 22.

[10] See 21 U.S.C. § 812.

[11] The complete text of Judge Young's opinion is available at http://www.druglibrary.org/schaffer/library/studies/YOUNG/index.html.

facts established that marijuana has an "accepted medical use" for treatment of (a) nausea resulting from chemotherapy, (b) spasticity resulting from multiple sclerosis and other causes, and (c) hyperparathyroidism.[12]

Additionally, the ALJ Opinion held that "there is accepted safety for use of marijuana under medical supervision." ALJ Opinion at 66. In particular, Judge Young noted that "[t]here was no record in the extensive medical literature describing a proven, documented cannabis-induced fatality," and that marijuana has an estimated LD-50 rating[13] of between 1:20,0000 and 1:40,0000. ALJ Opinion at 56-57. In lay terms, a smoker would have to consume 20,000 to 40,000 times as much marijuana as is contained in one marijuana cigarette (approximately 1,500 pounds) in fifteen minutes to induce a lethal response. ALJ Opinion at 57.

Judge Young concluded:

> [t]he evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA [the Drug Enforcement Administration] to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.

ALJ Opinion at 68. The Administrator of the DEA rejected the findings and recommendations of Judge Young, asserting

[12] Hyperparathyroidism is a condition causing increased calcium in the blood. Symptoms include nausea, vomiting, abdominal pain, skeletal pain, and weakened skeletal structure. See http://familydoctor.org, American Academy of Family Physicians, 2000.

[13] An LD-50 or LD-50 value is the amount of material that it takes to kill 50% of a test group in one dose. LD-50's are extrapolated for human dosage from animal studies.

that there was no scientific evidence showing that marijuana was better than other approved drugs for any specific medical condition, *see* 54 Fed. Reg. 53767 (Dec. 29, 1989). However, unlike Judge Young's findings, the DEA's conclusions lacked evidentiary support.

D. After Evaluating the Medical Evidence, Canada Now Permits Medical Marijuana

After a thorough review of medical evidence similar to that considered by the IOM and House of Lords, Canada adopted "Marihuanna Medical Access Regulations" on July 30, 2001.[14] These Regulations permit the possession and production of marijuana for medical purposes. The Regulations were developed by Health Canada, the federal agency responsible for helping the people of Canada maintain and improve their health. The agency promulgated the regulations after it had conducted its own survey of the scientific evidence regarding the therapeutic value of smoked marijuana.[15] While Health Canada's official position mirrors that of the American Medical Association (i.e.; that scientific

[14] Marihuanna Medical Access Regulations, SOR/2001-227, § 2 et seq. (June 14, 2001) (Can.), available at http://www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm. These regulations resulted from a year-long effort to address several issues revolving around the Ontario Court of Appeal's decision that the then existing exemptions to the Controlled Drugs and Substances Act were unconstitutional. See *R. v. Parker*, 2000 W.C.B.J. LEXIS 10970, 75 C.R.R. (2d) 233, 47 W.C.B. (2d) 116 (July 31, 2000) (available at http://www.ontariocourts.on.ca/decisions/2000/july/parker.htm);
Regulatory Impact Analysis Statement of the Marihuanna Medical Access Regulations amending the Narcotic Control Regulations (7/4/20021), available at http://ww.hc-sc.gc.ca/hecs-secs/ocma/index.htm.

[15] As of September 2004, 757 Canadians were currently allowed to possess marihuana for medical purposes, and 553 were authorized to persons are currently allowed to cultivate/produce marihuana for medical purposes. Health Canada, Office of Cannabis Medical Access. (http://www.hc-sc.gc.ca/hecssesc/ocma/stats/2004/sept/stats_sept-04.htm) (last visited October 11, 2004).

studies supporting the safety and efficacy of marijuana for therapeutic claims are, to date, inconclusive), it nevertheless recognized the potential value of marijuana for a determined group of patients. For that reason, the agency developed regulations to allow certain persons the ability to possess and cultivate marijuana for medical use.[16]

Consistent with the IOM, the House of Lords, and the weight of scientific evidence and clinical experiences attesting to marijuana's efficacy, Canada's law permits doctors to recommend and prescribe medical marijuana to certain persons who are suffering from severe pain, muscle spasms, anorexia, weight loss, and nausea, and who have not found relief from conventional therapies.[17]

II. MARIJUANA HAS RECOGNIZED ANALGESIC, ANTIEMETIC, ANTI-INFLAMMATORY, AND APPETITE-ENHANCING PROPERTIES

A. Marijuana Is An Effective Pain Killer

Patients with various pain syndromes claim significant relief from marijuana.[18] In fact, researchers have reported 18 of 23 patients suffering from intractable pain experienced significant pain reduction from cannabis extract that was sprayed under their tongue.[19] The validity of this

[16] Health Canada recently announced its plans to make government-certified marijuana available in local pharmacies to authorized patients, beginning with a pilot project being organized in British Columbia. Associated Press, *Canada Plans Pharmacy Marijuana Project* (March 21, 2004).

[17] Office of Cannabis Medical Access, *Medical Access to Marijuana – How the Regulations Work, available at* http://www.hc-sc.gc.ca/hecs-sesc/ocma/bckdr_1-0601.htm.

[18] *See, e.g.*, Lord Report §§ 5.26-5.30 at 24; IOM Report at 53-56.

[19] Clive Cookson, *High Hopes for Cannabis to Relieve Pain: British Association Science Festival in Glasgow*, Financial Times, Sept. 4, 2001,

finding is corroborated by studies in which cannabinoids have been shown to be effective analgesics in animal pain models.[20] This is particularly true for patients suffering from neuropathic pain.

Neuropathic pain is a symptom commonly associated with a variety of illnesses or conditions, including metastic cancer, HIV/AIDS, multiple sclerosis (MS), and diabetes, it can also be a side effect of the recommended treatments for various conditions. [21] Neuropathic pain in HIV/AIDS can be caused by HIV infection, or by the drugs used to treat it.[22] Currently approved treatments have substantial limitations in their effectiveness for relieving neuropathic pain. The absence of more effective and acceptable treatments for neuropathic pain is particularly problematic for certain HIV patients in which there are no good alternatives to antivirals

at National News pg. 4, *available at* http://news.ft.com/ft/gx.cgi/ftc?pagename=View&cid=FT3WWJOM6RC&live=true&query=cannabis

[20] *See, e.g.*, William J. Martin, *Basic Mechanisms of Cannabinoid-Induced Analgesia*, IASP Newsletter (International Association of the Study of Pain) Summer 1999, at 89 ("There is now unequivocal evidence that cannabinoids are antinociceptive [capable of blocking the appreciation or transmission of pain] in animal models of acute pain").

[21] Many of the reverse transcriptase and protease inhibitors commonly prescribed as part of the "AIDS cocktail" cause side effects including peripheral neuropathy, nausea, and vomiting. *See e.g.*, Physician's Desk Reference 889 (Didanosine), 895 (Stavudine) (54th ed. 2000).

[22] *See, e.g.*, David M. Simpson et al., *Selected Neurologic manifestations of HIV Infection: Dementia and Peripheral Neuropathy, improving the Management of HIV Disease*, Dec. 1999; Nathalie Do Quang-Cantagtrel et al., *Opioid Substitution to Improve the Effectiveness of Chronic Noncancer Pain Control: A Chart review*, 90 Anesthesia & Analgesia 933 (2000) (reporting opioid analgesics are effective for only 36% of patients, ineffective for 34% and intolerable for 30% of patients); Neurologic AIDS Research Consortium, *Peripheral Neuropathy (2004), available at* http://www.neuro.wustl.edu/narc/peri-neuropathy.html ("Treatment of neuropathic pain…is notoriously difficult. Even narcotics may not fully relieve [it].").

causing neuropathic pain, either due to drug resistance or other side effects from alternative drugs.[23]

B. Marijuana Is Effective In Treating Nausea, Anorexia And Wasting

Nausea, anorexia, and wasting are common symptoms of many cancers and HIV/AIDS. These symptoms are also the common adverse side effects of chemotherapy and other aggressive therapies used to treat those diseases and associated pain.[24] While other antiemetics may be available, not all patients respond to these therapies.[25] IOM at 153, 154.

Marijuana can provide critical relief for persons suffering from acute chronic nausea and vomiting who do not respond to conventional therapies.[26] As the Institute of Medicine explains,

[23] *Id.*

[24] The nausea-inducing properties of opioid analgesics used to treat pain are uncontroverted. *See, e.g.*, Am. Med. Ass'n, Encyclopedia of Medicine 98 (Charles B. Clayman ed., 1989) ("Nausea [and] vomiting ... may occur with narcotic analgesic drugs."); The Merck Manual of Diagnosis and Therapy (Robert Berkow ed., 17th ed. 1999) (same). *See also*, IOM Report at 151 (observing that patients receiving aggressive chemotherapy have "a 20-30% likelihood of experiencing acute emesis").

[25] *See, e.g.*, IOM Report at 157 ("Few therapies have proved successful in treatment of the AIDS wasting syndrome.").

[26] A New York State-sponsored study examined the effects of herbal cannabis on cancer chemotherapy patients who were unresponsive to standard antiemetics and found that 78% responded positively to cannabis. Vincent Vinciguerra et al., *Inhalation Marijuana as an antiematic for cancer chemotherapy*, N.Y.S.J. Med. 525 (Oct. 1988). Several other states have undertaken similar trials with similar results. *See generally* Richard E. Musty & Rita Rossi, *Effects of Smoked Cannabis and Oral Delta-0-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials*, 1 J. Cannabis Therapeutics 29 (2001). *See also* Lords Report § 5.12, at 21 (finding cannabis effective in alleviating acute nausea and vomiting).

> It is possible that the harmful effects of smoking marijuana for a limited period of time might be outweighed by the antiemetic benefits of marijuana, at least for patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis. Such patients should be evaluated on a case-by-case basis and treated under close medical supervision.

Id. at 154. As the Institute of Medicine noted, "[t]he critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but whether some group patients might obtain added or better relief from marijuana or cannabinoid drugs." IOM Report at 153. The IOM unequivocally concluded that there is indeed a group of patients to whom marijuana offers relief and that even the potentially harmful effects of smoking marijuana may be outweighed by the benefit provided.

Similarly, marijuana affords essential relief to patients suffering from anorexia and wasting syndromes for whom no other medications have been effective.[27]

C. Marijuana Is Effective In Treating Muscle Spasticity

Current treatments for painful muscle spasms, commonly associated with multiple sclerosis ("MS") and spinal cord injuries, have only limited effectiveness, and their use is complicated by various adverse side effects. IOM Report at 164. A growing body of clinical and preclinical

[27] IOM Report at 157 ("[Cannabinoids] could ... be beneficial for a variety of effects, such as increased appetite, while reducing the nausea and vomiting caused by protease inhibitors and the pain and anxiety associated with AIDS."); Lords Report § 5.15, at 22 (noting cannabis can counteract anorexia and wasting).

literature demonstrates that cannabinoids are effective in controlling the debilitating symptoms of MS.[28]

Conventional treatments have limited effectiveness for bladder dysfunction and pain associated with MS.[29] Marijuana, however, has been shown to be effective in alleviating these problems. Lord Report §§ 5.19-5.23, at 23. In addition, a survey of British and American MS patients reports that a significant majority experienced substantial improvements in controlling muscle spasticity and pain after ingesting marijuana.[30] An extensive neurological study likewise found that herbal cannabis provided relief from both muscle spasms and ataxia (loss of coordination), a multiple benefit not achieved by any other currently available medications.[31]

D. Marijuana Is Effective In Controlling Seizures

Clinical experience and emerging research also indicate that marijuana can help control epileptic seizures.[32] Cannabidiol (CBD), one of the primary (and

[28] *See* David Baker, et al., *Cannabinoids control spasticity and tremor in a multiple sclerosis model*, 404 Nature 117 (Mar. 2, 2000); Lords Report §§ 5.19 – 5.23, at 23. *See also* Mitch Earleywine, *Understanding Marijuana* 188 (Oxford University Press 2002).

[29] *See* Institute of Medicine, *Multiple Sclerosis: Current Status and Strategies for the Future* 143, 171 (Janet E. Joy & Richard B. Johnston, eds. 2001), *available at* http://www.nap.edu/books/0309072859/html.

[30] Paul Consroe *et al.*, *The Perceived Effects of Smoked Cannabis on Patients with Multiple Sclerosis*, 38 European Neurology 44 (1997) (reporting 96.5% of subjects with symptoms experienced lessened nighttime spasticity and 95.1% experienced reduced muscle pain, and greater than 70% of subjects reported decreased night leg pain, depression, tremor, anxiety, spasms on walking, leg weakness, trunk numbness, and facial pain).

[31] H.M. Meinck et al., *Effect of Cannabinoids on Spasticity and Ataxia in Multiple Sclerosis*, 236 J. Neurology 120 (1989).

[32] Lords Report § 5.31, at 24.

nonpsyhcoactive) cannabinoids present in the cannabis plant, appears to be of particularly beneficial, allowing patients who ingest it at certain times to avoid seizure activity. Some epileptics who cannot tolerate other antiseizure medications have been able to use marijuana to successfully control their seizures, without experiencing debilitating side effects.[33]

E. The Side Effects Of Marijuana Are No More Severe And Often Less Severe Than The Side Effects Of Many Currently Sanctioned Medications

The IOM examined the various potential harms associated with the medical use of marijuana and determined that "the acute side effects of marijuana use are within the risks tolerated for many medications," although its long-term chronic use may implicate concerns related to smoking. IOM Report at 126. Indeed, marijuana is considered to have a very wide margin of safety.[34] In contrast, many of the commonly prescribed antiemetic medications cause moderate to severe side effects in patients, including confusion and marked sedation.[35] The side effects of marijuana can be summarized as follows:

[33] *See* Jomar M. Cunha, *Chronic Administration of Cannabidiol to Healthy Volunteers and Epileptic Patients*, 21 Pharmacology 175 (1980); *R. v. Parker*, *supra* note 14, at *3 (holding that epileptic who suffered "frequent serious and potentially life-threatening seizures" and for whom surgery and conventional medications were unsuccessful is entitled to take marijuana to control seizures notwithstanding the prohibition of medicinal marijuana use under Canadian drug control statutes at that time).

[34] *See R. v. Parker*, *supra* note 14 at *48-49 (noting wide margin of safety of, and no evidence of overdose fatality from cannabis); ALJ Opinion at 56-60. *See also* Earleywine, Understanding Marijuana, supra note 28 at 186-189 & 195.

[35] *See, e.g.*, Physician's Desk Reference 3293, 3050 (54th ed. 2000) (side effects of Phenergan include sedation, confusion, and occasional nausea; side effects of Thorazine include suppression of cough reflex, drowsiness,

- Marijuana shows no indication of having immunosuppressant effect.[36]

- The ingestion of marijuana raises the heart rate, but there is no evidence that this increase poses a risk of cardiac arrest in patients who do not have pre-existing heart problems or who are otherwise in a high-risk group.[37]

- Some studies have suggested that marijuana smokers, like tobacco smokers, have a greater number of cellular and molecular abnormalities in the bronchial epithelium cells than nonsmokers, and that these changes are associated with an increased cancer risk.[38] However, "[t]here is conflicting evidence on whether regular marijuana use harms the small airways of the lungs," and it is therefore unlikely that the pulmonary side effects from smoking marijuana will be more severe than the side effects from smoking tobacco, a widely available and government-sanctioned drug.[39] Moreover, particularly for persons

fainting and dizziness upon initial dosing, and occasional muscle spasms).

[36] *See* IOM Report at 110; D. Abrams, *Short Term Effects of Cannabinoids on HIV-1 Infection*, Annals of Internal Medicine August 19, 2003; at 258-259; D. Abrams, *Short Term Effects of Cannabinoids on HIV-1 Viral Load*, presented at the 13th International AIDS Conference, Durban, South Africa (July 2000) (the use of cannabis does not adversely affect the immune system of HIV patients taking antiretroviral therapies).

[37] *See* IOM Report at 121.

[38] Sanford H. Barsky *et al.*, *Histopathologic and Molecular Alterations in Bronchial Epithelium in Habitual Smokers of Marijuana, Cocaine, and/or Tobacco*, 90 J. Nat'l Cancer Inst. 1198 (1998).

[39] IOM Report at 115. It is uncertain whether smoking cannabis, particularly for patients who may only consume enough to mitigate their symptoms, can actually cause pulmonary harm, such as chronic obstructive pulmonary disease (COPD) or lung cancer. *See* Lynn Zimmer and John P. Morgan, Marijuana Myths, Marijuana Facts 113-15 (Lindesmith Center 1997); Stephen Sidney *et al.*, *Marijuana use and*

suffering terminal illnesses, any such potential side effect is of little significance.

- The ability to titrate the dose of cannabinoids permits marijuana smokers to limit their intake of the drug to a dose that minimizes the impairment of their mental functioning.[40]

- The prescribed use of many common medications for pain, anxiety, and even hypertension may produce tolerance and physiological dependence; while some patients who use marijuana on a chronic basis may develop mild physiological dependence and experience withdrawal symptoms, these are minor in comparison to those associated with other medications routinely administered to treat serious illness.[41]

III. SYNTHETIC THC IS APPROVED AS A PRESCRIPTION DRUG, BUT OFTEN IS NOT AS EFFECTIVE, DESIRABLE, OR SAFE AS SMOKING MARIJUANA

Marinol – the brand name of dronabinol and a synthetic isomer of THC – is not a satisfactory treatment

cancer incidence, 8 Cancer Cause & Control 722 (1997).

[40] *See infra* Lords Evidence, note 44 at 178.

[41] IOM Report at 90-91 (stating that compared to tobacco and alcohol, dependence on cannabis is relatively rare and that marijuana withdrawal "has been reported only in a group of adolescents in treatment for substance abuse problems and in a research setting where subjects were given marijuana or THC daily [and then precipitously withdrawn from it]." Even then, the withdrawal symptoms "were short lived" and "[i]n four days they had abated.") (*citing* T.J. Crowley, *et al.*, *Cannabis dependence, withdrawal, and reinforcing effects among adolescents with conduct symptoms and substance use disorders*, 50 Drug & Alcohol Dependence 27-37 (1998)); M. Haney, *et al.*, *Abstinence symptoms following smoked marijuana in humans*, 141 Psychopharmacology 395-404 (1999); R. Jones, *et al.*, *Clinical studies of tolerance and dependence*, 282 Annals of New York Academy of Sciences 221-239).

alternative for many patients for at least four reasons. First, while Marinol is approved by the Food and Drug administration to treat nausea and vomiting associated with cancer chemotherapy and anorexia associated with weight loss in patients with AIDS, its pill form sometimes undermines its effectiveness. For instance, paradoxically, the pill is often regurgitated before it can suppress vomiting. 64 Fed. Reg. 35,928 (1999). Moreover, many patients suffering from the symptoms for which Marinol is approved, are unable to swallow the drug. As a result, patients often are unable to ingest a sufficient quantity of the drug to benefit from its effects. *See e.g.* ALJ Opinion at 11. In contrast, neither vomiting nor the inability to swallow diminishes the efficacy of THC delivery by smoking marijuana.

Second, unlike smoked marijuana, Marinol delays relief. Marinol is ingested – while the active ingredients in smoked marijuana are inhaled – patients in need of immediate relief must often suffer for an extended period of time before Marinol takes effect. By contrast, smoking marijuana is a more efficient delivery mechanism that provides the blood stream with the drug's therapeutic benefits, almost instantaneously, resulting in prompt relief for patients:

> Smoking . . . delivers rapid drug effect, whereas the THC capsule takes effect slowly, and its results are variable. There are many symptoms for which a quick-acting drug is ideal such as pain, nausea and vomiting.

Opening Statement of Stanley J. Watson, Jr., Institute of Medicine News Conference Marijuana and Medicine: Assessing the Science Base (Mar. 17, 1999).[42]

[42] The complete text is available at http://www.4.nationalacademics.org (search for "Watson and Marijuana").

Third, smoking marijuana has less debilitating psychoactive side effects than Marinol. After being swallowed, Marinol is delivered first to the stomach and then to the liver where it is metabolized into 11-hyddroxy-deta-THC. This metabolite is three times more psychoactive than THC delivered to the lungs by smoked cannabis. IOM Report at 36.[43] Therefore, not only do patients on Marinol suffer a prolonged wait for relief, but they also often experience harsh psychoactive side effects which they are then unable to mitigate from ingesting a full dose of the THC. By contrast, patients who smoke marijuana can regulate their dose of THC, achieving the desired therapeutic effect without experiencing the same intensity of psychoactive side effects.

> [S]moking . . . is actually a very good route of administration, in some ways; it is very effective, there is a very rapid absorption, and the patients have a great deal of control over how much they take. They learn to titrate.[44]

Fourth, marijuana contains other effective active ingredients not contained in Marinol. Marinol is composed of only a single compound, THC. By contrast, marijuana is a complex botanical substance, containing over 400 components and approximately 66 cannabinoids, which fall

[43] Citing Razdan, R., *Structure-activity relationships in cannabinoids*, 38 Pharmacology Rev. 75-149 (1986).

[44] Select Committee on Science and Technology, the House of Lords, Sess. 1997-98, Cannabis: The Scientific and Medical Evidence: Evidence (Nov. 4 1998) ("Lords Evidence"). As an alternative to smoking, the therapeutic components of the cannabis plant can be inhaled using vaporizer devices. Vaporizers heat cannabis to 150-200 degrees Centigrade, evaporating the cannabinoids and other volatile oils. This temperature is below the burning point of combustible plant material, so smoke is not generated. This technology has been available for over 20 years. John M. McPartland & Patty L. Pruitt, *Medical Marijuana and its Use by the Immunocompromised*, 3 Alternative Therapies 39, 43 (1997).

into 10 groups of closely related cannabinoids. IOM Report at 24. The main cannabinoids include delta9-THC, delta8-THC, Cannabidiol ("CBD"), cannabinol, cannabichromene, and cannabigerol. IOM Report at 24-25. Several of these cannabinoids – not just THC – have therapeutic applications, either alone or in combination with others.

> Herbal cannabis contains a mixture of active compounds. It is too early to be certain if the therapeutic action [of cannabis] is limited to one compound . . . Cannabis may contain a synergistic mixture of active compounds. This is particularly likely now that we know there are at least two receptor specified loci of action.[45]

Lords Evidence at 32. For example, CBD, which is not psychoactive, has been shown to have potential neuroprotective and anti-inflammatory uses.[46]

So while a viable option for many patients, Marinol's limitations make the "choice" of using it illusory in fact for some of the most seriously ill patients.

[45] *See also* John M. McPartland & Patty L. Pruitt, *Side Effects of Pharmaceuticals Not Elicited by Comparable Herbal Medicines: The Case of Tetrahydrocannabinol and Marijuana*, 5 Alternative Therapies 57, 60 (1999).

[46] *See* A.J. Hampson et al., *Cannabidiol and (-)delta-9-tetrahydrocannabinol are neuroprotective antioxidants [sic]*, 95 Proceedings of the National Academy of Sciences 8268 (July 1998) (addressing neuroprotection use); A.M. Malfait, et al., *The nonpsychoactive cannabis constituent cannabidiol is an oral anti-arthritic therapeutic in murine collagen-induced arthritis*, 97 Proceedings of the National Academy of Science 9561 (Aug. 2000) (addressing anti-inflammatory/anti-arthritic uses). These articles are available at http://www.pnas.org/all.shtml (search for the desired author).

IV. THE PERSONAL EXPERIENCES OF BOTH MEDICAL PROVIDERS AND PATIENTS SUPPORT SCIENTIFIC AND GOVERNMENT FINDINGS THAT MARIJUANA CAN BE AN EFFECTIVE THERAPEUTIC

Support for the medicinal value of marijuana is widespread. In a 1991 Harvard survey of more than 2400 oncologists, over 40% of respondents had recommended the use of marijuana for the control of nausea and vomiting to at least one cancer patient. Almost half considered cannabis to be therapeutically useful and would prescribe it if it was lawful to do so.[47] The AMA's Council on Scientific Affairs, since at least 1997, has cautiously acknowledged the potential medical efficacy of marijuana and called for additional

> [a]dequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficiency and the application of such results to the understanding and treatment of disease.[48]

In addition, many physicians find that marijuana's efficacy rivals or surpasses that of other antiemetic drugs for certain patients.[49] When comparing marijuana to Marinol,

[47] *See* Richard E. Doblin & Mark A.R. Kleiman; *Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes*, 9 J. Clin. Oncol. 1314-1319 (1991).

[48] Report 10 of the Council on Scientific Affairs (I-97), *Medical Marijuana*28, available at http://www.ama-assn.org/ama/pub/article/2036-4299.html. The recommendation for additional research was affirmed at the AMA's 2001 Annual Meeting. Report 6 of the Council on Scientific Affairs (A-01), *Medical Marijuana*, available at http://www.ama-assn.org/ama/pub/article/2036-6124.html.

[49] *See, e.g.*, Sallan, S.E., Zinberg, N.E. (1975). *Antiemetic effects of delta-9-tetrahydrocannabinol in patients receiving cancer chemotherapy*. New England Journal of Medicine, 293, 795-797 cited in Earleywine, M.,

44% of oncologists believed that smoked marijuana was more effective.[50]

While many physicians who recommended marijuana do not consider it the first line of defense against the symptoms or side effects of their patients' serious illnesses, they do recognize it as a valuable medication for those patients who cannot tolerate or who do not respond well to conventional medications.

CONCLUSION

Convincing scientific evidence and clinical experience demonstrate that smoking marijuana provides medical benefits that are not replicated by synthesized drugs. Recent government sponsored studies in the United States and Great Britain confirm this conclusion. Canada has now approved usage of medical marijuana. In addition, the collective weight of scientific studies, patients' personal experiences, physicians' clinical successes, and government-sponsored studies provides a convincing basis for the medical use of cannabis by certain patients. For the foregoing reasons, the decision of the Court of Appeals should be affirmed.

Respectfully submitted,

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[50] *See* Doblin, *supra*, note 47.

APPENDIX

Description of Amici:

Amicus Curiae **Lymphoma Foundation of America** is a national non-profit organization devoted to helping lymphoma patients and their families. Lymphoma refers to cancers of the lymph system and approximately 62,000 new cases are diagnosed each year. The Lymphoma Foundation provides counseling, support groups, referrals and public education, and it maintains a public web site. *See* <http://www.lymphomahelp.org/> Based on its history with thousands of patients, it is the Lymphoma Foundation's experience that, for some patients, marijuana is an efficacious and at times necessary treatment for nausea, vomiting, and lack of appetite – serious, sometimes life-threatening symptoms that afflict many lymphoma patients undergoing chemotherapy and radiation.

Amicus Curiae **HIV Medicine Association of the Infectious Diseases Society of America** ("HIVMA") is a national organization of more than 2600 physicians and other health professionals who practice HIV medicine. HIVMA is committed to ensuring that public policies related to HIV prevention, research and treatment are grounded in science and informed by social justice.

Amicus Curiae **American Medical Student Association** ("AMSA") is the oldest and largest independent association of physicians-in-training in the United States. Founded in 1950, AMSA is a student-governed, non-profit organization committed to representing the concerns of physicians-in-training. AMSA began under the auspices of the American Medical Association (AMA) to provide medical students a chance to participate in organized medicine. Starting in 1960, the association refocused its energies on the problems of the

medically underserved, inequities in our health-care system and related issues in medical education. With approximately 50.000 members, including medical and premedical students, residents and practicing physicians, AMSA is committed to improving medical training as well as advancing the profession of medicine.

Amicus Curiae **Barbara Roberts, Ph.D.**, served as a senior policy analyst and acting deputy director for demand reduction in the Office of National Drug Control Policy of the White House ("ONDCP") for ten years, until August 2003. During her tenure with the ONDCP, Dr. Roberts specifically recommended that the National Institute of Medicine of the National Academy of Sciences ("IOM") be commissioned to undertake a review of the scientific evidence regarding therapeutic applications of marijuana. Dr. Roberts supports the IOM Report and its recommendations. Additionally, Dr. Roberts has been a treating clinician for the National Football League in its Program for Substance Abuse since 1997. Dr. Roberts is currently a Clinical Associate Professor in the Department of Psychiatry at Georgetown University Medical Center, and she serves as President of the District of Columbia Psychological Association for the 2004-2005 term. Dr. Roberts is also an appointed member of the licensing board for the District of Columbia Board of Psychology, which is the agency responsible for overseeing the practice of psychology in Washington, D.C. Dr. Roberts believes in the importance of scientific research into the medical uses of marijuana.

Amicus Curiae **Irvin Henry Rosenfeld** was born in 1953 and diagnosed at age 10 with multiple congenital cartilaginous exostosis, a disease causing the continuous growth of bone tumors, and the generation of new tumors, on ends of most of the long bones of his body. He was told he would probably not survive into adulthood. In an attempt to

treat the painful symptoms of the disease, he was prescribed high doses of opioid analgesics, muscle relaxants, and anti-inflammatory medications, which he took on a daily basis, but which had minimal efficacy and produced debilitating side effects. In 1971, Mr. Rosenfeld began using smoked herbal cannabis with the approval and under the supervision of a team of physicians. Mr. Rosenfeld found the cannabis highly efficacious in alleviating pain, reducing swelling, relaxing muscles and veins that surround the bone tumors, and preventing hemorrhaging. In November 1982, the United States government, operating under the Compassionate Care IND Program, and at the request of Mr. Rosenfeld's physicians, began supplying Mr. Rosenfeld with herbal cannabis for medical use – *i.e.*, to treat his condition. Mr. Rosenfeld was the second patient accepted into the Compassionate Care IND Program and he is the longest-surviving participant. Presently, the federal government supplies Mr. Rosenfeld with a 150-day supply of medical cannabis, totaling 66 ounces per shipment. Mr. Rosenfeld smokes 12 marijuana cigarettes a day to control and alleviate the symptoms of his disease. During the more 33 years that Mr. Rosenfeld has used herbal cannabis as a medicine, he has experienced no adverse side-effects (including no "high"). Further, Mr. Rosenfeld has been able to discontinue his prescription medications and has worked successfully for the past 18 years as a stockbroker handling millions of dollars in accounts. Mr. Rosenfeld and his physicians believe that but for medical cannabis Mr. Rosenfeld might not be alive or, at the very least, would be bed-ridden.